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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,033	03/02/2004	Sandra Kelly-Aehle	MEG-210.1 US-1	1250
29425	7590	08/31/2005	EXAMINER	
LEON R. YANKWICH YANKWICH & ASSOCIATES 201 BROADWAY CAMBRIDGE, MA 02139			HINES, JANA A	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 08/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/791,033	KELLY-AEHLER, SANDRA
	Examiner	Art Unit
	Ja-Na Hines	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 02 March 2004.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-16 and 22-34 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-16 and 22-34 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-7 and 22-34 are drawn to a method of delivering a protein to a domestic bird wherein the enteropathogenic bacteria is selected from the group consisting of ATCC 39961 and ATCC 39962, classified in class 424, subclass 258.1.
  - II. Claims 1-6, 13-14 and 22-34 are drawn to a method of delivering a protein to a domestic bird wherein the enteropathogenic bacteria is ATCC 67923, classified in class 424, subclass 258.1.
  - III. Claims 1-6, 13, 15-16 and 22-34 are drawn to a method of delivering a protein to a domestic bird wherein the enteropathogenic bacteria is selected from the group consisting of ATCC 55117 and ATCC 55115, classified in class 424, subclass 258.1.
  - IV. Claims 1-5, 8 and 22-34 are drawn to a method of delivering a protein to a domestic bird wherein the enteropathogenic bacteria is selected from the group consisting of ATCC 53864, ATCC 53865 and ATCC 53866, classified in class 424, subclass 258.1.
  - V. Claims 1-5, 11-12 and 22-34 are drawn to a method of delivering a protein to a domestic bird wherein the enteropathogenic bacteria is selected from the group consisting of ATCC 55110, ATCC 55115, ATCC 55113, ATCC 55119, and ATCC 55118, classified in class 424, subclass 258.1.

VI. Claims 1-5, 9-10 and 22-34 are drawn to a method of delivering a protein to a domestic bird wherein the enteropathogenic bacteria is selected from the group consisting of ATCC 67537, ATCC 53681, ATCC 67538, ATCC 53680, ATCC 53678 and ATCC 67813, classified in class 424, subclass 258.1.

2. The inventions are distinct, each from the other because of the following reasons:

(a) Inventions I and any of II-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of delivering a protein to a domestic bird wherein the enteropathogenic bacteria is *Salmonella typhimurium* selected from the group consisting of ATCC 39961 and ATCC 39962 and any other method, such as the method of group II, is unrelated as they utilize different enteropathogenic bacterium which demonstrates that each method has a different function and mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the different enteropathogenic bacteria differ significantly within each of the methods. These bacterial strains within the methods constitute patentably distinct inventions. For instance, the groups are directed to different enteropathogenic bacterium which are distinct physically, structurally, and functionally and are therefore patentably distinct, each group from the other, and one bacterium is not required to practice the other. Each group comprises separate and distinct strains that do not

share a substantial structural feature disclosed as being essential to the utility of the invention. For instance only group III comprises strains of *Salmonella typhi* which have been made avirulent by an inactivating mutation in the structural *cpr* gene. Therefore, each method is unrelated. For these reasons the Inventions I and any of II-VI are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. In the instant case, the search of the methods and enteropathogenic bacteria are not coextensive. In cases such as this one where descriptive bacterial information is provided, the strains are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the bacterial strain of interest there may be journal articles devoted solely to a particular strain which would not have described the other strains. Searching, therefore is not coextensive. In addition, the claims include specific ATCC deposit numbers whose search requires an extensive analysis of the art and the retrieved art will require an in-depth analysis of technical literature. As such, it would be burdensome to search the inventions of groups I and II-VI together.

3. Because these inventions are distinct for the reasons given above, and have divergent subject matter, the search required for Group I is not required for Groups II-VI. Moreover, the search required for each group is not required for the other groups since each group requires a different non-patent literature search due to each group

comprising different enteropathogenic bacterial strains within the claimed method steps, restriction for examination purposes as indicated is proper.

4. Should applicant traverse on the ground that the enteropathogenic bacterial strains are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the strains to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines   
August 17, 2005